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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,296	03/13/2001	Vladimir Efimov	AM-00102.P.1-US	2109
7590 01/19/2005			EXAMINER	
Biotechnology Law Group 658 Mansoian Avenue Solana Beach, CA 92075			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/805,296	EFIMOV ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Thomas McKenzie, Ph.D.	1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 108-113 is/are pending in the application.
- 4a) Of the above claim(s) 97-107 and 114-129 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 108,109,112 and 113 is/are allowed.
- 6) ☒ Claim(s) 110 and 111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5,10,16</u> | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. This action is in response to amendments filed on 11/05/04. Applicant has amended claims 108 and 110. Applicant has canceled claims 97-107 114-129. Claims 108-113 were previously rejected.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/04 has been entered.

***Response to Amendment***

3. Applicants' cancellation of the non-elected claims addresses the issue raised in point #4 of the previous office action. Applicants have amended claim 108 to read on B<sup>1</sup> and B<sup>2</sup> as hydrogen and nucleases only. Since all nucleobases are purine and pyrimidine molecules, this overcomes the objection made in point #5. This also overcomes the objection made in point #6, since Applicants' no longer claim "non-naturally occurring nucleobases". The definition of such a phrase is no longer essential material. This also overcomes the indefiniteness rejection made in point #8.

***Abstract***

4. Applicant is still reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." The abstract is too generic. Examiner suggests claim 108, including the figure.

Applicants remark they wish this objection held in abeyance.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 110 and 111 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "a phosphono peptide nucleic acid monomer" is indefinite. Again, nowhere in the specification is this term defined *verbatim*. What is the structure of this radical? In lines 24-27, page 2 Applicants introduce the abbreviation "pPNAs" for phosphono peptide nucleic acid. In lines 16-19, pages 12, Applicants define "a phosphono peptide nucleic

acid" but fail to specify if this is a monomer. They use open language "comprising" "such as". In lines 23-26, page 13, Applicants define "monomer unit of a peptide nucleic acid" but fail to specify if this is a phosphorus containing peptide. The definition includes "nucleobase (or nucleobase analogue, nucleobase-binding unit, ligand, intercalator, reporter group or label)". The indefiniteness of these terms has been discussed in the previous office action. The nucleobase "is covalently attached to an amino acid or amino acid derivative or analog". Does amino acid refer to the twenty naturally occurring amino acids, which are coded for in DNA, or are all compounds containing any acid and amine group intended? The issue of derivative or analogue was discussed previously. The three structures **II-IV**, pages 20, 22, and 24 are described as hydroxyproline and aryl phosphono peptide nucleic acid monomers. Is this what is meant? The Examiner understands that hydroxyproline is an amino acid, which may be incorporated into a peptide, but hydroxyproline itself is not a peptide. An aryl group is not a peptide but structure IV apparently may contain additional peptides in radicals G and E. The Examiner suggests using structures **II-IV**, if that is what is intended.

Applicants point pages 37, 40, 42, and 44 of the specification as indicating what they intend. Page 37 defines "a hydroxyproline peptide nucleic acid phosphono peptide nucleic acid dimer" or "HypNA-pPNA" dimer". This does not

define *ipso verba* the meaning of "a phosphono peptide nucleic acid monomer". A monomer and a dimer are not the same thing. Removal of a hydroxyl proline from Formula (VIII) leaves  $N(T) C(R^{12})(R^{13}) C(R^{14})(R^{15}) N(A^2-B^2) C(R^{16})(R^{17}) P(O)(O^-)E$ . There is no way to divide this dimer radical in half to determine which is the monomer under discussion.

Page 40 discloses "a phosphono peptide nucleic acid-hydroxyproline peptide nucleic acid dimer" or "pPNA-HypNA" dimer". Page 42 discloses "a serine peptide nucleic acid-phosphono peptide nucleic acid dimer" or "SerNA-pPNA" dimer". Page 44 discloses "a phosphono peptide nucleic acid-serine peptide nucleic acid dimer" or "pPNA-SerNA" dimer". These three dimer formulas certainly contain the phrase " phosphono peptide nucleic acid" but do not *ipso verba* define what is meant by "a phosphono peptide nucleic acid monomer". The structures themselves are internally inconsistent.

Removal of a hydroxyl proline from Formula (IX) leaves  $G-N(T) C(R^{12})(R^{13}) C(R^{14})(R^{15}) N(A^2-B^2) C(R^{16})(R^{17}) P(Q)(O^-)E$ . This differs by the presence of variable G and Q from the dimer discussed above. Again, there is no way to divide this dimer radical in half to determine which is the monomer under discussion.

When the Examiner mentally removes what appears to be a serine residue from "a serine peptide nucleic acid-phosphono peptide nucleic acid dimer" (X) what remains is a lengthy residue containing  $A^2-B^2$  attached to a nitrogen atom. While this is the same residue found on page 37 it differs from the residue found on page 40.

When the Examiner mentally removes what appears to be serine from "a phosphono peptide nucleic acid-serine peptide nucleic acid dimer" (XI) what remains is  $G-N(T) C(R^{12})(R^{13}) C(R^{14})(R^{15}) N(A^2-B^2) C(R^{16})(R^{17}) P(Q)(O^-)E$ . This is the same residue as found on page 40 but differs from those shown on pages 37 and 42. Which residue represents the structure of "a phosphono peptide nucleic acid monomer"? Are both structures being claimed? Are there others? How does one determine the monomer structure being claimed from the dimer structures shown in the specification?

In a previous telephone interview, Applicants proposed incorporating the formulas of their desired phosphono peptide radical into the structures but have failed to do so.

***Allowable Subject Matter***

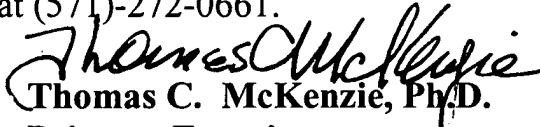
6. Claims 108, 109, 112, and 113 are allowed. Claims 110 and 111 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd

paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

7. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

8. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.

  
Thomas C. McKenzie, Ph.D.  
Primary Examiner  
Art Unit 1624

TCMcK/me